

Regulatory Affairs

VOLTAREN® (diclofenac sodium)

25 mg and 50 mg Gastro-resistant tablets
75 mg and 100 mg Prolonged-release tablets
12.5 mg, 25 mg, 50 mg and 100 mg Suppositories

National Succinct Statement (NSS)

Version 3.0

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VOLTAREN®

Important note: Before prescribing, please consult full prescribing information: <https://www.swissmedicinfo.ch/>.

Disclaimer: This link will contain the most updated product information approved by the reference country.

Presentation:

<i>Pharmaceutical form</i>	<i>Dosage strength(s)</i>	<i>Active substance (equivalent to/corresponding to)</i>	<i>Abbreviation</i>
Gastro-resistant tablets	25 mg and 50 mg	diclofenac sodium	GRT
Prolonged-release tablets	75 mg and 100 mg	diclofenac sodium	PRT
Suppositories	12.5 mg, 25 mg, 50 mg, and 100 mg	diclofenac sodium	SUP

Indications:

Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis including spondylarthritis

Painful syndromes of the vertebral column.

Non-articular rheumatism.

Painful post-traumatic and post-operative inflammation and swelling, e.g. following dental or orthopaedic surgery.

Painful and/or inflammatory gynaecological conditions, e.g. primary dysmenorrhoea or adnexitis.

Migraine attacks (suppositories).

Acute attacks of gout (gastro-resistant coated tablets, suppositories, oral drops).

As an adjunct in acute painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis (gastro-resistant coated tablets, suppositories, oral drops).

In keeping with standard therapeutic principles, the underlying disease should be treated with specific therapy as appropriate. Fever alone is not an indication.

Dosage/Administration

As a general recommendation, the dose should be individually adjusted. Adverse effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see "Warnings and precautions").

Usual dosage

Adults

Gastro-resistant coated tablets, suppositories

The starting dose for Voltaren gastro-resistant coated tablets and Voltaren suppositories is usually 100-150 mg/day. In milder cases and for long-term therapy, 75-100 mg/day are normally sufficient.

The total daily amount is generally given in 2–3 divided doses. In order to avoid nocturnal pain and morning stiffness, treatment with the gastro-resistant coated tablets during the daytime can be supplemented by the administration of a suppository at bedtime (up to a maximum daily dose of 150 mg).

In primary dysmenorrhoea, the daily dosage should be individually adjusted and is generally 50-150 mg/day. Treatment should be started at 50-100 mg/day and, if necessary, may gradually be increased over the course of several menstrual cycles to a maximum of 150 mg/day.

The gastro-resistant coated tablets should be swallowed with liquid, preferably before meals; they must not be divided or chewed.

The suppositories should be inserted well into the rectum, preferably after a bowel movement.

Treatment of migraine attacks with Voltaren suppositories should be started with a dose of 100 mg at the first sign of an impending attack. Additional suppositories up to a maximum of 50 mg may be taken on the same day, if required. If further treatment is required on the following day, the maximum daily dosage should be limited to 150 mg, given in divided doses.

Prolonged-release coated tablets

The usual daily dose of Voltaren Retard is 100-150 mg, i.e. one 100 mg prolonged-release coated tablet, or two 75 mg prolonged-release coated tablets. In milder cases and for long-term therapy, one 75 mg or 100 mg prolonged-release coated tablet per day is normally sufficient. If symptoms are most pronounced at night or in the morning, Voltaren Retard should preferably be taken in the evening.

The prolonged-release coated tablets should be swallowed whole with liquid, preferably with meals.

Special dosage instructions

Established cardiovascular disease or significant cardiovascular risk factors

Treatment with Voltaren is generally not recommended in patients with established cardiovascular disease or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension or significant risk factors for cardiovascular disease should be treated with Voltaren only after careful consideration, and only at doses of up to 100 mg daily if treated for more than 4 weeks (see "Warnings and precautions").

Patients with hepatic impairment

Voltaren is contraindicated in patients with hepatic failure (see "Contraindications").

No specific studies have been carried out in patients with hepatic impairment; therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering Voltaren to patients with mild to moderate hepatic impairment (see "Warnings and precautions").

Patients with renal impairment

Voltaren is contraindicated in patients with renal failure (GFR <15 ml/min/1.73 m²; see "Contraindications").

No specific studies have been carried out in patients with renal impairment; therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering Voltaren to patients with renal impairment (see "Warnings and precautions").

Elderly patients

No adjustment of the starting dose is generally required for elderly patients. However, caution is indicated on basic medical grounds, especially for frail elderly patients or those with a low body weight (see "Warnings and precautions").

Children and adolescents

Voltaren oral drops are particularly suitable for paediatric use since they enable the dosage to be individually tailored to body weight within the recommended range (1 drop = 0.5 mg).

For adolescents and for children aged 1 year or older, the daily dosage, depending on the severity of the disorder, is 0.5 to 2 mg/kg body weight, given in 2-3 divided doses. For the treatment of juvenile rheumatoid arthritis, the daily dosage can be increased up to a maximum of 3 mg/kg body weight, given in several divided doses.

The maximum daily dose of 150 mg should not be exceeded.

The bottle containing the suspension should always be shaken thoroughly before the drops are administered.

Voltaren must not be given to children under 1 year of age.

Voltaren 50 mg gastro-resistant coated tablets and Voltaren 50 mg and 100 mg suppositories are not recommended for use in children due to their dosage strength.

Voltaren 25 mg gastro-resistant coated tablets may be used in these patients.

Voltaren 75 mg and 100 mg prolonged-release coated tablets are not suitable for children and adolescents.

Voltaren 12.5 mg or 25 mg suppositories are recommended for use in children and adolescents below 14 years of age. Due to their dosage strength, Voltaren 50 mg suppositories are not recommended in children and adolescents below 14 years of age. Voltaren 100 mg suppositories are not suitable for children and adolescents.

Contraindications: ♦ Known hypersensitivity to diclofenac, or to any of the excipients indicated under "Composition". ♦ Active gastric or intestinal ulcer, bleeding or perforation. ♦ Last trimester of pregnancy. ♦ Hepatic failure. ♦ Renal failure (GFR <15 mL/min/1.73 m²). ♦ Severe cardiac failure. ♦ Proctitis (*SUP only*).

Warnings and precautions: ♦ Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. ♦ Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. ♦ Caution recommended when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents or SSRIs. ♦ Caution recommended when used after gastro-intestinal surgery. ♦ Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and only at doses of up to 100 mg daily, especially when treatment continues for more than 4 weeks. ♦ Monitoring of blood counts recommended during prolonged treatment. ♦ Caution recommended in patients with asthma, seasonal allergic rhinitis,

swelling of the nasal mucosa or chronic pulmonary diseases. ♦ Risks of serious allergic reactions including anaphylactic/anaphylactoid reactions. Cases of Kounis syndrome have been reported in patients treated with NSAIDs. Kounis syndrome involves cardiovascular symptoms due to an allergic or hypersensitivity reaction, including narrowing of the coronary arteries, and may potentially lead to a myocardial infarction. ♦ Caution recommended in patients with impaired hepatic function (including porphyria). ♦ Monitoring of liver function during prolonged treatment. ♦ Beware of severe fluid retention and edema. ♦ Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. ♦ Caution is indicated in the elderly. ♦ Avoid use with other systemic NSAIDs including COX-2 inhibitors. ♦ May mask signs and symptoms of infection.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy

- ♦ Should not be used in the first and second trimester of pregnancy, unless absolutely necessary.
- ♦ Contraindicated during the third trimester of pregnancy.

Lactation

- ♦ Should not be used by breast-feeding mothers. If treatment is essential, the infant should be switched to bottle feeding.

Infertility

- ♦ Not recommended to use in women attempting to conceive as it may impair female fertility.

Adverse drug reactions:

♦ **Common (≥ 1 to $<10\%$):** Headache, light-headedness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, increased transaminases, rash, fluid retention, oedema, application site irritation (**SUP only**).

♦ **Uncommon* (≥ 0.1 to $<1\%$):** myocardial infarction, cardiac failure, chest pain, palpitations (*frequency reflects data from long-term treatment with a high dose of 150 mg/day).

♦ **Rare (≥ 0.01 to $<0.1\%$):** Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema, proctitis (**SUP only**).

♦ **Very rare ($<0.01\%$):** Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion,

anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual disturbances and impairment*, blurred vision*, diplopia*, tinnitus, impaired hearing, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/ hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensitivity reaction, purpura, Henoch-Schoenlein purpura, pruritus, acute kidney injury (including acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis, hemorrhoids (**SUP only**).

***Visual effects:** If symptoms of visual disturbances occur during diclofenac treatment, an ophthalmological examination may be considered to exclude other causes.

◆Frequency not known: Kounis syndrome, drug rash with eosinophilia and systemic symptoms (DRESS).

Interactions:

◆Monitoring of serum lithium or digoxin levels recommended if used concomitantly. ◆Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs.). ◆Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. ◆Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g., potassium-sparing diuretics, ciclosporin, tacrolimus, trimethoprim. ◆Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g., voriconazole), and CYP2C9 inducers (e.g., rifampicin). ◆Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. ◆Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. ◆Monitoring of phenytoin plasma concentrations is recommended if used concomitantly.

Packs and prices: Country specific.

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